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TO: Assistant Commissioner for Patent
Washington, DC 20231

ATTN: Examiner T. Saidha

FAX NO.: 1-703-308-0294

DATE: November 26, 2001

FROM: Samuel B. Abrams

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We are transmitting herewith a COMMUNICATION for filing
in:

Application of: Harrington et al.

Application No.: 09/586,744

Group Art Unit: 1652

Filed: June 2, 2000

Examiner: T. Saidha

For: MAMMALIAN FLAP-SPECIFIC
ENDONUCLEASE

Attorney Docket NO.: 9584-017

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30.605
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICEApplication of: Harrington *et al.*

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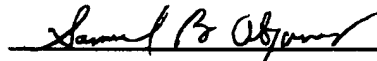
Sir:

During an Examiner Interview conducted on October 5, 2001 between Examiner Tekchand Saidha and Attorneys for Applicants, Samuel B. Abrams and Scott A. Warren, a helpful discussion was held concerning claims to subject matter disclosed in the specification via incorporation by reference, and whether such claims are fully supported in accordance with the written description requirement of 35 U.S.C. § 112, first paragraph. Below, Applicants summarize the points discussed.

Claims to double flap substrate structures and methods of using the same are presented in the present application. As originally filed, the present application referred to double flap substrate structures by virtue of incorporation by reference of Harrington and Lieber (1995) *J. Biol. Chem.* 270:4503 ("Harrington and Lieber"). Harrington and Lieber is incorporated by two references in the specification. The first recites:

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Also incorporated herein by reference are: ... Harrington and Lieber (1995) *J. Biol. Chem.* 270. Col. 20, line 66 to col. 21, line 3

The second refers explicitly to the teaching of the DNA flap substrates:

DNA flap substrates, cleavage and binding reactions and the like are practiced with reference to the Experimental Examples and ... Harrington and Lieber (1995) *J. Biol. Chem.* 270: 4503. Col. 39, line 65 to col. 40, line 3

According to the Manual of Patent Examining Procedure (MPEP)

[t]he information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. *Replacing the identified material incorporated by reference with the actual text is not new matter.*

MPEP § 2163.07(b), emphasis added.

Thus, according to the MPEP, the text of Harrington and Lieber should be treated as part of the text of the application as filed. In addition, amending the specification to actually include the text of Harrington and Lieber is permitted and does not constitute new matter.

While information that is incorporated by reference is to be treated as if it were part of the text of the application as filed, such information is not entirely the same as information repeated verbatim in the text of the application. In the MPEP, there is a distinction made between "essential" subject matter and "nonessential" subject matter. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art. Essential subject matter is defined as subject matter that is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention or (3) describe the best mode. See MPEP § 608.01(p)(I)(A).

The incorporation of "essential" material by reference to a non-patent publication is termed an "improper incorporation." See MPEP § 608.01(p)(I)(A)(2).

However, the MPEP provides the following remedy for such an "improper incorporation:"

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the reference. *In such a case, the applicant will be required to*

amend the specification to include the material incorporated by reference.

See MPEP § 608.01(p)(I)(A)(2), emphasis added.

Thus, when there is an "improper incorporation," the applicant is required to amend the specification to add the incorporated subject matter, and further, such amendment, because it does not affect the filing date of the application, does not introduce new matter into the specification.

It was precisely such an amendment that was made by Applicants in the present application when the text of Harrington and Lieber was added to the text of the specification.

In summary, amendment of the specification to include text of Harrington and Lieber is specifically allowed by the Patent Office. Since such amendment does not introduce new matter, and since the included text is treated as if it were *already present in the application as originally filed*, the pending claims that rely on the incorporated text are fully supported by the original application.

Accordingly, reconsideration of these issues by the Examiner is respectfully requested.

Respectfully submitted,

Date November 26, 2001

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